

Best Available Copy

SHEET 1 OF 13

Form PTO-1449

U.S. Department of Commerce,  
Patent and Trademark Office

Atty. Docket

Serial No.

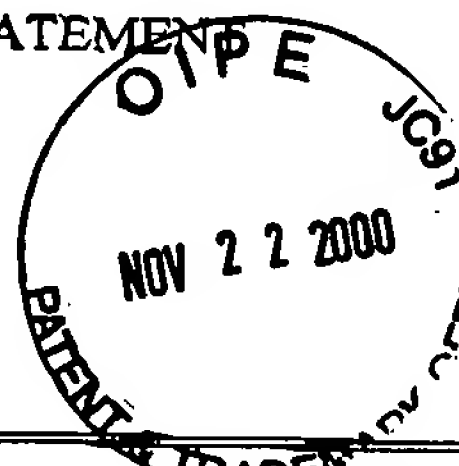
09/707,766

P-2769-US6

Not Yet Known

INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT

(Use several sheets if necessary)



Applicant

Mitchell S. Steiner et al.

Filing Date

Group

November 8, 2000

## U.S. Patent Documents

*Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
BF	A	4,990,538	February 5, 91	Harris et al.			
BF	B	5,788,964	August 4, 98	Baral et al.			
BF	C	5,650,425	July 22, 97	Biegnon et al.			
BF	D	4,696,949	Sept 29, 87	Toivola et al.			

## Foreign Patent Documents

*Examiner Initial		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
BF	E	98/58634	December 30, 98	WO				
BF	F	415 623 A2	March 6, 1991	EP				
BF	G	616 529 B1	September 28, 94	EP				
BF	H	94/12162	June 9, 1994	PCT WO				
BF	I	095875	Dec 7, 1995	BPE EP				
BF	J	95/26720	Oct 12, 1995	PCT WO				
BF	K	98/58634	Dec 30, 1998	PCT WO				

## OTHER ART

(Including Author, Title, Date, Pertinent Pages, Etc.)

*Examiner Initial		
BF	L	Martin R. Schneider et al. "Nonsteroidal Antiestrogens and Partial Estrogens with Prostatic Tumor Inhibiting Activity", Cancer Research Clinical Oncology Springer-Verlag 1986, J Cancer Res Clin Oncol (1986) 112: 258-265, p. 258-265,
BF	M	Celine Martel et al. "Binding Characteristics of Novel Nonsteroidal Antestrogens to the Rat Uterine Estrogen Receptors", Pergamon, J. Steroid Biochem. Molec. Bio., Vol 64, No. 3-4, pp. 199-205, 1998.
BF	N	Ritva Valavaara, MD, PhD "Reliability of Estrogen Receptors in Predicting Response To Antiestrogens", Oncology, Volume 11 Number 5 Supplement No. 4 p. 14-18.
BF	O	Richard Gams, MD "Phase III Trials of Toremifene vs Tamoxifen" Oncology Volume 11, Number 5, Supplement 4, May 1997
BF	P	Christian Rohlf et al. "Prostate Cancer Cell Growth Inhibition by Tamoxifen Is Associated With Inhibition of Protein Kinase C and Induction of p21" The Prostate 37:51-59 (1998) ©1998 Wiley-Liss, Inc
BF	Q	Nevalanine et al. "Hormone Regulation of Human Prostate in Organ Culture" Cancer Res, vol. 53, no. 21, 1993, pages 5199-5207, XO002117653.

Examiner

Date Considered

Blessing Fubara

2-20-02

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with your communication to applicant.

Best Available Copy

SHEET 2 OF 13

Form PTO-1449

U.S. Department of Commerce,  
Patent and Trademark Office

Atty. Docket No.

Serial No.

09/707,764

P-2769-US6

Not Yet Known

Applicant

Mitchell S. Steiner et al.

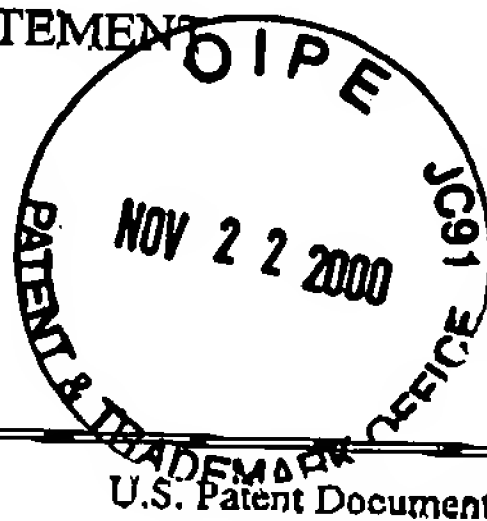
Filing Date

Group

November 8, 2000

INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT

(Use several sheets if necessary)



U.S. Patent Documents

*Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
BF	R	5,491,173	Feb. 13, 1996	Toivola et al.			
BF	S	5,571,534	Nov. 5, 1996	Jalonen et al.			
BF	T	5,605,700	Feb. 25, 1997	DeGregorio et al.			
BF	U	5,595,722	Jan. 21, 1997	Grainger et al.			
BF	V	5,599,844	Feb. 4, 1997	Grainger et al.			
BF	W	5,629,007	May 13, 1997	Audia et al.			
BF	X	5,635,197	June 3, 1997	Audia et al.			
BF	Y	5,595,985	Jan. 21, 1997	Labrie			
BF	Z	4,329,364	May 11, 1982	Neri et al.			
BF	AA	4,474,813	Oct. 2, 1984	Neri et al.			

## Foreign Patent Documents

*Examiner Initial		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No

## OTHER ART

(Including Author, Title, Date, Pertinent Pages, Etc.)

*Examiner Initial	AB	Greenwald "Expanding Horizons in Breast and Prostate Cancer Prevention and Early Detection", in J. Cancer Education, 1993, Vol. 8, No. 2, pages 91-107.
BF	AC	Brawley et al., "Chemoprevention of Prostate Cancer" in Urology, 1994, Vol. 43, No. 5.
BF	AD	Kelloff et al., "Introductory Remarks: Development of Chemopreventive Agents for Prostate Cancer" in Journal of Cellular Biochemistry, 1992, Supplement 16H: 1-8.
BF	AE	Lucia et al., "Chemopreventive Activity of Tamoxifen, N-(4-Hydroxyphenyl)retinamide, and the Vitamin D Analogue Ro24-5531 for Androgen-promoted Carcinomas of the Rat Seminal Vesicle and Prostate" in Cancer Research, 1995, vol. 55, pages 5621-5627.
BF	AF	Potter et al., "A Mechanistic Hypothesis for DNA Adduct Formation By Tamoxifen Following Hepatic Oxidative Metabolism" in Carcinogenesis, 1994, Vol. 15, No. 3, pages 439-442.

Examiner

Blessing Fabrice

Date Considered

2-20-02

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with your communication to applicant.



Form PTO-1449

U.S. Department of Commerce,  
Patent and Trademark Office

Atty. Docket No.

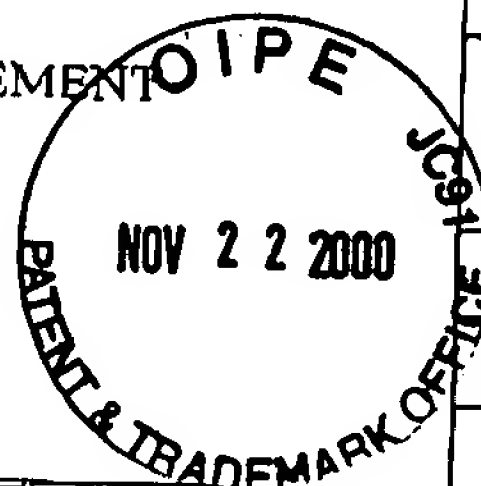
Serial No.

09/707,764

## INFORMATION DISCLOSURE STATEMENT

BY APPLICANT

(Use several sheets if necessary)



P-2769-US6

Not Yet Known

Applicant

Mitchell S. Steiner et al.

Filing Date

Group

November 8, 2000

## U.S. Patent Documents

*Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate

## Foreign Patent Documents

*Examiner Initial	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No

## OTHER ART

(Including Author, Title, Date, Pertinent Pages, Etc.)

*Examiner Initial	AO	Simard et al., "Keoxifene Shows Pure Antiestrogenic Activity in Pituitary Gonadotrophs", Molecular and Cellular Endocrinology 39, 1985, pages 141-144.
BF	AP	Perry "High Dose Toremifene for Estrogen and Progesterone Receptor Negative Metastatic Breast Cancer: a Phase II Trial of the Cancer and Leukemia Group B (CALGB)", in Breast Cancer Res Treat - 1995; 26(1): 25-40
BF	AQ	Hietanen T "Open Phase II Study of High-Dose Toremifene as First-Line Therapy for Advanced Breast Cancer" in Oncology - May 1997; 11(5 Suppl 4): 37-40.
BF	AR	Black et al. "Uterine Bioassay of Tamoxifen, Trioxifene and a New Estrogen Antagonist (LY117018) in Rats and Mice" in Life Sciences, 1980, Vol. 26, pp. 1453-1458
BF	AS	Moore et al. "Regulation of Cytoplasmic Dihydrotestosterone Binding in Dog Prostate by 17 $\beta$ -Estradiol", in J. Clin. Invest. © The American Society for Clinical Investigation, Inc., Vol. 63 March 1979, pages 351-357.
BF	AT	Shirai et al. "Effects of Testosterone, Dihydrotestosterone and Estrogen on 3,2'-Dimethyl-4-Aminobiphenyl-Induced Rat Prostate Carcinogenesis" in Int. J Cancer: 57, 224-228 (1994)
BF	AU	Greenwald et al. "Breast Cancer Prevention and Early Detection", pages 93-106.
BF	AV	Shenfeld et al. "Androgen Deprivation Therapy", Chapter 37, Section III/Prostate Cancer, pages 467-477

Examiner

Date Considered

Blessing Fubara

2-20-02

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with your communication to applicant.

Best Available Copy

SHEET 5 OF 13

Form PTO-1449

U.S. Department of Commerce,  
Patent and Trademark Office

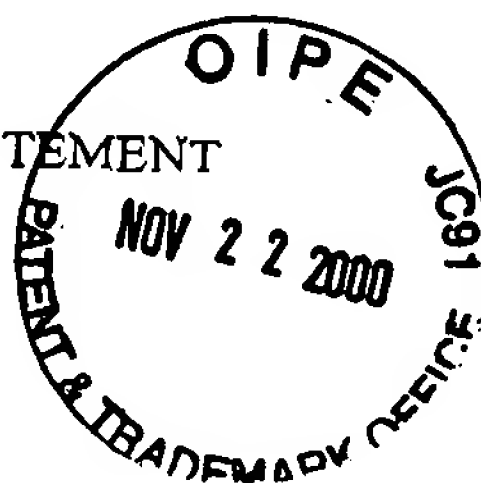
Atty. Docket No.

Serial No.

09/707,766

INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT

(Use several sheets if necessary)



P-2769-US6

Not Yet Known

Applicant

Mitchell S. Steiner et al.

Filing Date

Group

November 8, 2000

## U.S. Patent Documents

*Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate

## Foreign Patent Documents

*Examiner Initial	Document Number	Date	Country	Class	Subclass	Translation
						Yes No

## OTHER ART

(Including Author, Title, Date, Pertinent Pages, Etc.)

*Examiner Initial	AW	Jordan VC "Toremifene As An Anticancer Agent", Cancer Invest 1990; 8(2):271
BF	AX	Karlsson S. et al. "A Two-Year Dietary Carcinogenicity Study Of The Antiestrogen Toremifene In Sprague-Dawley Rats" Drug Chem Toxicol 1996 Nov; 19(4): 245-66.
BF	AY	Powles TJ "Status Of Antiestrogen Breast Cancer Prevention Trials" Oncology (Huntingt) 1998 Mar; 12(3 Suppl 5): 28-31.
BF	AZ	Moon RC et al. "Chemoprevention of MNU-Induced Mammary Tumorigenesis by Hormone Response Modifiers: Toremifene, RU 16117, Tamoxifen, Aminoglutethimide and Progesterone", Anticancer Res 1994 May-June; 14(3A): 889-93.
BF	BA	Nevalainen MT et al. "Expression and Hormone Regulation Of Prolactin Receptors in Rat Dorsal and Lateral Prostate", Endocrinology 1996 Jul; 137(7): 3078-88.
BF	BB	Foekens JA et al. "Expression Of Prostate-Specific Antigen (PSA) Correlates With Poor Response To Tamoxifen Therapy In Recurrent Breast Cancer", Br J Cancer 1999 Feb; 79(5-6): 888-94.
BF	BC	Brandes LJ et al. "Salutary Clinical Response Of Prostate Cancer To Antiandrogen Withdrawal: Assessment Of Flutamide In An In Vitro Paradigm Predictive Of Tumor Growth Enhancement", Clin Cancer Res 1997 Aug; 3(8): 1357-61.
BF	BD	Miyata E et al. "Effects Of Tamoxifen, An Antiestrogen, On Rat Prostate Carcinogenesis by 3,2'-Dimethyl-4-Aminobiphenyl And Testosterone Do Not Support An Estrogen Role In Testosterone Promotion", Prostate 1997 Apr 1;31(1):9-13.
BF	BE	Pienta KJ et al. "A Phase II Evaluation Of Oral Tamoxifen And Intermittent Intravenous Vinblastine In Hormone-Refractory Adenocarcinoma Of The Prostate", Am J Clin Oncol 1996 Oct; 19(5):500-3.
BF	BF	Pienta KJ et al. "Inhibition Of Prostate Cancer Growth By Vinblastine And Tamoxifen", Prostate 1995 May; 26(5): 270-4.
BF	BG	Lippman SM et al. "Cancer Chemoprevention", J Clin Oncol 1994 Apr; 12(4):851-73.
BF	BH	Szarka CE et al. "Chemoprevention Of Cancer", Curr Probl Cancer 1994 Jan-Feb; 18(1):6-79.

Examiner

Blessing Fuhara

Date Considered

2-20-02

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with your communication to applicant.



Best Available Copy

SHEET 6 OF 13

Form PTO-1449

U.S. Department of Commerce,  
Patent and Trademark Office

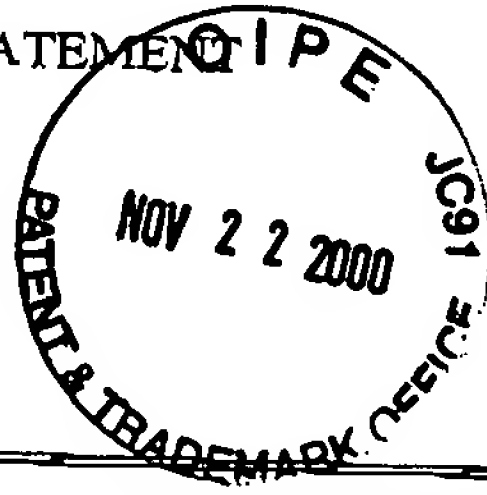
Atty. Docket No.

Serial No.

09/707,766

INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT

(Use several sheets if necessary)



P-2769-US6

Not Yet Known

Applicant

Mitchell S. Steiner et al.

Filing Date

Group

November 8, 2000

## U.S. Patent Documents

*Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate

## Foreign Patent Documents

*Examiner Initial	Document Number	Date	Country	Class	Subclass	Translation
						Yes No

## OTHER ART

(Including Author, Title, Date, Pertinent Pages, Etc.)

*Examiner Initial	BI	Yu H et al. "Induction Of Prostate Specific Antigen Production By Steroids And Taxoxifen In Breast Cancer Cell Lines", Breast Cancer Res Treat 1994; 32(3):291-300.
BF	BJ	Horton J et al. "Tamoxifen In Advanced Prostate Cancer: An ECOG Pilot Study", Prostate 1988; 12(2):173-7.
BF	BK	Kangas L "Development And Biochemical Pharmacology Of Toremifene, An Antiestrogenic Antitumor Drug", Acta Obstet Gynecol Scand 1991; 70(4-5): 399.
BF	BL	Anttila M et al. "Pharmacokinetics Of The Novel Antiestrogenic Agent Toremifene In Subjects With Altered Liver And Kidney Function" Clin Pharmacol Ther 1995 Jun; 57(6):628-35.
BF	BM	Kamat AM et al. "Chemoprevention Of Urological Cancer", The Journal Of Urology, Vol. 161. 1748-1760. June 1999, p. 1748-1760.
BF	BN	Fleton SA "Potential New Antiestrogens For The Treatment Of Breast Cancer", Highlights in Oncology Practice Vol. 15, No. 2, 1997 p. 47-52
BF	BO	Nevalainen M.T. et al. "Estrogen and Prolactin Regulation of Rat Dorsal and Lateral Prostate in Organ Culture", Endocrinology, Vol. 129, No. 2 pages 612-618
BF	BP	Moon R.C. et al. "Chemoprevention of MNU-Induced Mammary Tumorigenesis by Hormone Response Modifiers: Toremifene, RU 16117, Tamoxifen, Aminoglutethimide and Progesterone", Anticancer Research 14: 889-894 (1994)
BF	BQ	Price K. R. et al. "Naturally Occurring Oestrogens in Food - A review", Food Additives and Contaminants, 1985, Vol. 2, No. 2, 73-106.

Examiner

Blessing Fubara

Date Considered

2-20-02

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with your communication to applicant.

Best Available Copy

SHEET 7 OF 13

Form PTO-1449

U.S. Department of Commerce,  
Patent and Trademark Office

Atty. Docket No.

Serial No.

09/707,766

P-2769-US6

Not Yet Known

Applicant

Mitchell S. Steiner et al.

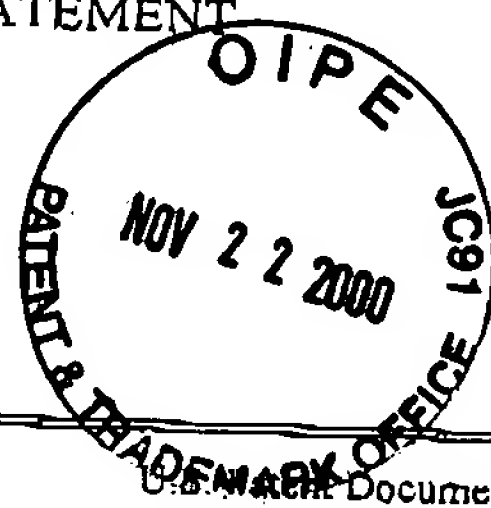
Filing Date

Group

November 8, 2000

INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT

(Use several sheets if necessary)



U.S. Patent Documents

*Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate

## Foreign Patent Documents

*Examiner Initial	Document Number	Date	Country	Class	Subclass	Translation
						Yes No

## OTHER ART

(Including Author, Title, Date, Pertinent Pages, Etc.)

*Examiner Initial	BR	Prins Gail S. "Developmental Estrogenization Of The Prostate Gland", Prostate: Basic and Clinical Aspects p. 245-263 (1997).
BF	BS	Kuiper George G. J. M. "Cloning Of A Novel Estrogen Receptor Expressed In Rat Prostate And Ovary", Proc. Natl. Acad. Sci USA Vol. 93, pp. 5925-5930, June 1996 Biochemistry.
bf	BT	Kuiper George G. J. M. "Interaction Of Estrogenic Chemicals and Phytoestrogens With Estrogen Receptor $\beta$ ", Endocrinology Vol. 139, No. 10 (1998).
bf	BU	Horton John et al. "Tamoxifen In Advanced Prostate Cancer" An ECOG Pilot Study", The Prostate 12: 173-177 (1988).
bf	BV	Hayes "A Randomized Comparison Of Tamoxifen, Trioxifene And A New Estrogen Antagonist (LY117018) In Rats And Mice" (n Life Sciences, 1980, vol. 26, pp. 1453-1458.

Examiner

Blessing Fubara

Date Considered

2-20-02

\*EXAMINER: Initial if reference considered. whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with your communication to applicant.

Best Available Copy

SHEET 8 OF 13

Form PTO-1449

U.S. Department of Commerce,  
Patent and Trademark Office

Atty. Docket No.

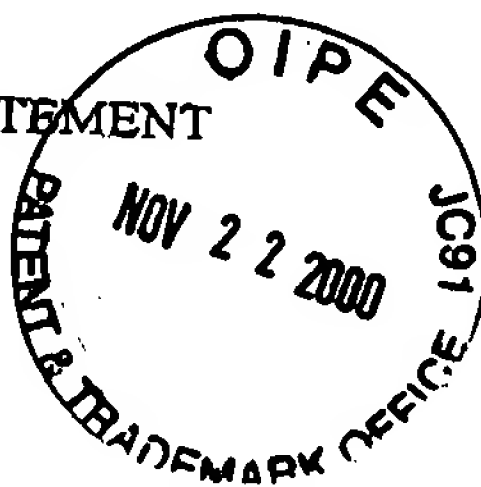
Serial No.

09/707,766

## INFORMATION DISCLOSURE STATEMENT

BY APPLICANT

(Use several sheets if necessary)



P-2769-US6

Not Yet Known

Applicant

Mitchell S. Steiner et al.

Filing Date

Group

November 8, 2000

## U.S. Patent Documents

*Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate

## Foreign Patent Documents

*Examiner Initial	Document Number	Date	Country	Class	Subclass	Translation
						Yes No

## OTHER ART

(Including Author, Title, Date, Pertinent Pages, Etc.)

*Examiner Initial	BW	Dhar JD et al. "Estrogen, Androgen and Antiestrogen Responses In The Accessory Organs Of Male Rats During Different Phases Of Life", Endocr Res 1998 May; 24(2): 159-69.
BE	BX	West Neal B et al. "Estrogen and Progestin Receptors And Aromatase Activity In Rhesus Monkey Prostate" Endocrinology, Vol. 1. 123, (1998)
BE	BY	Strauss L "Genistein Exerts Estrogen-Like Effects In Male Mouse Reproductive Tract", Molecular and Cellular Endocrinology 144 (1998)83-93, Elsevier Science Ireland Ltd.
BE	BZ	Strom Sara S. et al. "Phytoestrogen Intake and Prostate Cancer: A Case-Control Study Using A New Database", Nutrition and Cancer, 33(1), 20-25. (1999).
BE	CA	Kellof GJ et al. "Strategies For Chemoprevention Of Prostate Cancer", Prostate Cancer and Prostate Disease (1998) 5. 107.
BE	CB	Buelke-Sam Judy et al. "The Selective Estrogen Receptor Modulator, Raloxifene: An Overview Of NonClinical Pharmacology and Reproductive Development Testing", Reproductive Toxicology Vol. 12, No. 3 pp. 217-221, 1998.
BE	CC	Hobisch Alfred "Metastatic Lesions From Prostate Cancer Do Not Express Oestrogen And Progesterone Receptors" J. Pathol. 182: 356-361, 1997.
BE	CD	Albert David S. et al. "An Overview Of Clinical Cancer Chemoprevention Studies With Emphasis On Positive Phase III Studies" Overivew of Diet Cancer 6928-6975 (1995)

Examiner

Blessing Fubara

Date Considered

2-20-02

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with your communication to applicant.



Best Available Copy

SHEET 9 OF 13

Form PTO-1449

U.S. Department of Commerce  
Patent and Trademark Office

Atty. Docket No.

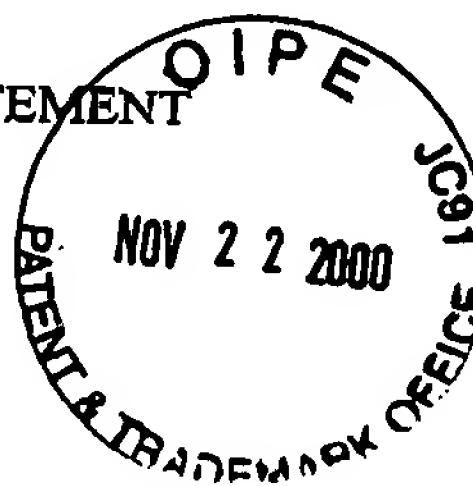
Serial No.

09/707,766

## INFORMATION DISCLOSURE STATEMENT

BY APPLICANT

(Use several sheets if necessary)



P-2769-US6

Not Yet Known

Applicant

Mitchell S. Steiner et al.

Filing Date

Group

November 8, 2000

## U.S. Patent Documents

*Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate

## Foreign Patent Documents

*Examiner Initial	Document Number	Date	Country	Class	Subclass	Translation
						Yes No

## OTHER ART

(Including Author, Title, Date, Pertinent Pages, Etc.)

*Examiner Initial	CE	Cheng E et al. "Endocrinology Of The Prostate", Prostate Diseases, chapter 5- p. 57-71.
bs	CF	Bonkhoff H et al. "Estrogen Receptor Expression In Prostate Cancer and Premalignant Prostatic Lesions", American Journal of Pathology, Vol. 155, No. 2 August 1999.
bs	CG	"New Research Approaches In The Prevention And Cure Of Prostate Cancer", American Association For Cancer Research.
bs	CH	Xiaolin Zi et al. "Silibinin Decreases Prostate-Specific Antigen With Cell Growth Inhibition Via G1 Arrest, Leading To Differentiation Of Prostate Carcinoma Cells: Implications For Prostate Cancer Intervention", Proc. Natl. Acad. Sci. USA Vol. 96, pp. 7490-7495, June 1999. Medical Sciences.
bs	CI	Landstrom M, et al. "Inhibitory Effects Of Soy and Rye Diets On The Development Of Dunning R3327 Prostate Adenocarcinoma in Rats, The Prostate 36: 151-161 (1998).
bs	CJ	Buelke-Sam J. et al. "The Selective Estrogen Receptor Modulator, Raloxifene: An Overview Of NonClinical Pharmacology And Reproductive And Developmental Testing", Reprod Toxicol 1998 May-June; 12(3):217-21.
bs	CK	Treinen KA et al. "An Evaluation Of The Novel Selective Estrogen Receptor Modulator, Idoxifene, For Effects On Reproduction In Rats And Rabbits", Toxicol Sci 1998 Feb; 41(2):199-207.
bs	CL	Boehm S et al. "Estrogen Suppression As A Pharmacotherapeutic Strategy In The Medical Treatment Of Benign Prostatic Hyperplasia: Evidence For Its Efficacy From Studies With Mepartricin" Wien Klin Wochenschr 1998 Dec 11; 110(23):817-23.

Examiner

Blessing Fubara

Date Considered

2-20-02

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with your communication to applicant.

Best Available Copy

SHEET 10 OF 13

Form PTO-1449

U.S. Department of Commerce  
Patent and Trademark Office

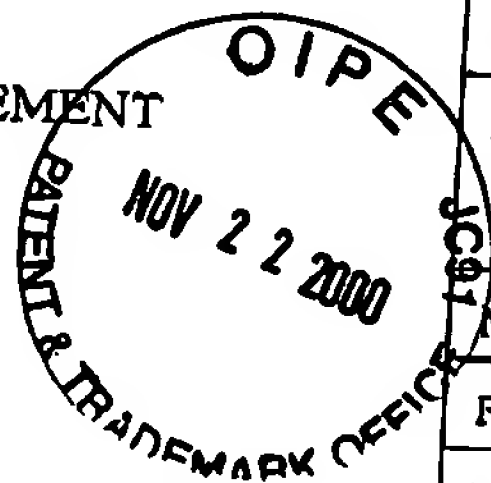
Atty. Dock No.

Serial No.

09/707,766

INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT

(Use several sheets if necessary)



P-2769-US6

Not Yet Known

Applicant

Mitchell S. Steiner et al.

Filing Date

Group

November 8, 2000

## U.S. Patent Documents

*Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate

## Foreign Patent Documents

*Examiner Initial	Document Number	Date	Country	Class	Subclass	Translation
						Yes No

## OTHER ART

(Including Author, Title, Date, Pertinent Pages, Etc.)

*Examiner Initial	CM	Bergan RC et al. "A Phase II Study Of High-Dose Tamoxifen In Patients With Hormone-Refractory Prostate Cancer." Clin Cancer Res 1999 Sep; 5(9): 2366-73.
BS	CN	Chang William Y et al. "Estrogen Receptor- $\beta$ : Implications For The Prostate Gland" The Prostate 40:115-124 (1999)
BS	CO	Shughrue Paul J. et al. "Comparative Distribution Of Estrogen Receptor- $\alpha$ (Er- $\alpha$ ) And $\beta$ (Er- $\beta$ ) mRNA In The Rat Pituitary, Gonad, And Reproductive Tract" Steroids 63: 498-504, 1998, Elsevier Science Inc.
BS	CP	Prins Gail S. et al. "Neonatal Estrogen Exposure Up-Regulates Estrogen Receptor Expression In The Developing And Adult Rat Prostate Lobes*", Endocrinology 138: 1801-1809, 1997)
BS	CQ	Hempstock J. et al. "Growth Inhibition Of Prostate Cell Lines In Vitro By Phyto-Oestrogens", British Journal Of Urology (1998). 82.
BS	CR	Awoniyi Caleb A. et al. "Neonatal Exposure To Coumestrol, A Phytostrogen, Does Not Alter Spermatogenic Potential In Rats", Endocrine, vol. 7, no. 3, 337-341, December 1997.
BS	CS	"Chemoprevention Of Prostate Cancer: Guidelines For Possible Intervention Strategies", Journal of Cellular Biochemistry, Supplement 16H:140-145 (1992).
BS	CT	"When Is Intervention Warranted?", Journal Of Cellular Biochemistry, Supplement 16H:138-139 (1992).
BS	CU	"Editorial: A New Actor In The Estrogen Receptor Drama-Entre ER- $\beta$ ", Endocrinology Vol. 138, No. 3, (1997).
BS	CV	Kuiper George G. J. M. et al. "Comparison Of The Ligand Binding Specificity And Transcript Tissue Distribution Of Estrogen Receptors $\alpha$ and $\beta$ ", Endocrinology Vol. 138, No. 3, 863-870 (1997).
BS	CW	Colletta Anthony A. et al. "Alternative Mechanisms Of Action Of Anti-Oestrogens" Breast Cancer Research and Treatment 31: 5-9, 1994.
BS	CX	Griffiths K. et al. "Further Insights Into Endocrine Disease - Diet and Prostate Disease" An IPHC Teaching Programme.

Examiner

Blessing Fubara

Date Considered

2-20-02

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with your communication to applicant.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PTO/SB/08A (10-96)

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449B/PTO		Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)		Application Number	Not Yet Known
		Filing Date	November 8, 2000
		First Named Inventor	STEINER, Mitchell S.
		Group Art Unit	
		Examiner Name	
		Attorney Docket Number	P-2769-US6
Sheet	11 of 13		

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.†	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
bf	CY	Boyle, P. et al "Epidemiology of Prostate Cancer Chemoprevention" Genetic and Environmental Factors In Prostate Cancer Geneels, European Urology 1999; 35; pgs 270-376.	<input type="checkbox"/>
BF	CZ	Lancet Conference "The Challenge of Breast Cancer" Brugge 1994	<input type="checkbox"/>
BF	DA	Mobbs B. G. et al. "Concentration and Cellular Distribution of Androgen Receptor in Human Prostatic Neoplasia: Can Estrogen Treatment Increase Androgen Receptor Content?" J. Steroid Biochem. vol. 19, No. 3, pp. 1279-1290, 1983	<input type="checkbox"/>
BF	DB	Jordan Craig V. "Antiestrogenic Action of Raloxifene and Tamoxifen: Today and Tomorrow" Journal of the National Cancer Institute, Vol. 90, No. 13, July 1, 1998	<input type="checkbox"/>
bf	DC	Hard Gordon C. et al. "Major Difference in the Hepatocarcinogenicity and DNA Adduct Forming Ability between Toremifene and Tamoxifen in Female Crl: CD(BR) Rats1", Cancer Research 53, 4534-4541, October 1, 1993	<input type="checkbox"/>
BF	DD	Bostwick, M.D. "Prostatic Intraepithelial Neoplasia and Atypical Adenomatous Hyperplasia", Prospective Origins of Prostate Carcinoma, 1996 American Cancer Socly, pgs 330-335.	<input type="checkbox"/>
BF	DE	Warri, Ann M. et al. "Apoptosis in Toremifene-Induced Growth Inhibition of Human Breast Cancer Cells In Vivo and In Vitro", Journal of the National Cancer Institute, Vol. 85, No. 17, September 1, 1993, pgs 1412-1418	<input type="checkbox"/>
BF	DF	Zaridze David G. et al. "International Trends in Prostatic Cancer", Int. J. Cancer: 33, 223-230 (1984).	<input type="checkbox"/>
BF	DG	Bostwick David G. et al. "Reversibility of Prostatic Intraepithelial Neoplasia: Implications for Chemoprevention" Surrogate Endpoint Biomarkers for Clinical Trials of Prostate Cancer Chemoprevention, European Urology 1999; 36:492-495.	<input type="checkbox"/>

Under the Paperwork Reduction Act of 1996, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO

**Complete If Known**

**(use as many sheets as necessary)**

Sheet

13

of

13

Application Number

## Not Yet Known

**Filing Date**

**November 8, 2000**

**First Named Inventor**

**STEINER, Mitchell S.**

## Group Art Unit

**Examiner Name**

Attorney Docket Number

**P-2769-US6**

## U.S. PATENT DOCUMENTS

[illegible]

# FOREIGN PATENT DOCUMENTS

[illegible]

**Examiner  
Signature**

Blessing Fubara

Date Considered

2-26-02

\***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.**

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.  
 Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE  
 PTO/SB/08A (10-96) OMB 0651-0031

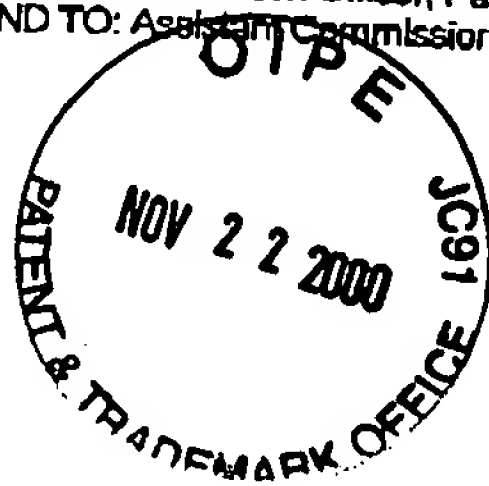
BF	DH	Kelloff, Gary J. "Chemoprevention of Prostate Cancer: Concepts and Strategies", European Urology 1999; 35: 342-350.	<input type="checkbox"/>
BF	DI	Leav Irwin et al. "Androgen-Supported Estrogen-Enhanced Epithelial Proliferation in the Prostates of Intact Noble Rats", The Prostate 15:23-40 (1989)	<input type="checkbox"/>
BF	DJ	Rohlf C et al. "Prostate Cancer Cell Growth Inhibition by Tamoxifen Is Associated With Inhibition of Protein Kinase C and Induction of p21 <sup>waf/cip1</sup> ", The Prostate 37: 51-59 (1998)	<input type="checkbox"/>
BF	DK	Kellen J. A. "The Effect of Toremifene on the Expression of genes in a Rat Mammary Adenocarcinoma", In Vivo 10: 511-514 (1996).	<input type="checkbox"/>
BF	DL	Montandon F. et al. "Comparison of DNA Reactivity of the Polyphenylethylene Hormonal Agents Diethylstilbestrol, Tamoxifen and Toremifene in Rat and Hamster Liver", Archives of Toxicology (1994) 68: 272-275.	<input type="checkbox"/>
BF	DM	Krieg M et al. "Androgens and Estrogens: Their Interaction With Stroma And Epithelium Of Human Benign Prostatic Hyperplasia And Normal Prostate", J. Steroid Biochem. Vol. 19, No. 1. Pp. 155-161, 1983	<input type="checkbox"/>

Examiner Signature	Blessing Fabara	Date Considered	2-20-02
--------------------	-----------------	-----------------	---------

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



**This Page is Inserted by IFW Indexing and Scanning  
Operations and is not part of the Official Record**

**BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☒ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☒ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:**

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**